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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,010	09/23/1999	YING LUO	A-68294/DJB/	7948

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	27

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/404,010	LUO ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 December 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11-23,25 and 27-33 is/are pending in the application.

4a) Of the above claim(s) 11-23 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 25, 27-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 December 2002 has been entered. Claims 11-23, 25, and 27-33 are pending in this application. Claims 11-23 are withdrawn from consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 25 and 27-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The claims are drawn to a nucleic acid encoding a kinase. Applicant teaches that the kinase is involved in the cell cycle and thus may be used to screen for compounds that affect the cell cycle. However, Applicant has provided no teachings as to how the polypeptide encoded by the polynucleotide affects cell division and thus how it could be used to identify modulators of the cell cycle. What is shown is that the encoded protein interacts with TRAF4. While Applicant states in paper no. 13 that TRAF4 is amplified in human primary breast cancer and is required for normal cell proliferation , Applicant provides no teachings as to the effect of the interaction of TRAF4 and Mkinase. There is no indication as to what effect TRAF4 has on the activity of Mkinase, or what the consequences of any effect might be. Thus there is "no specific benefit in currently available form" associated with this interaction. Similarly, there is no specific and substantial utility associated with screens for modulators of this interaction, since one of skill would not know what activity would be expected to be modulated by a molecule so identified. There is no "real world" use associated with the study of modulators of a protein whose significance itself is unknown. Applicant has provided evidence that Mkinase can phosphorylate a MAP kinase substrate, but no teachings as to its effects, if any, on cell proliferation. There is no indication, for example, as to what physiological substrates Mkinase phosphorylates and what effect this phosphorylation has on the cell cycle. Thus, clearly, further research would be required to ascertain the role of Mkinase in the cell cycle, and thus how compounds that affect it would affect the cell cycle. See Brenner v. Manson, noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The instant specification teaches that the claimed nucleic acid encodes a protein with a kinase domain and homology to MAP kinase and CDK families (p. 5) and Applicant has additionally provided evidence that the kinase phosphorylates the MAP kinase substrate myelin basic protein. Absent evidence that it phosphorylates the same site as MAP kinases, this teaching is not sufficient to identify the protein as a MAP kinase. However, such identification would not provide the polypeptide and encoding polynucleotides with a well-established utility. MAP kinases are involved in signaling by many cell-surface receptors, and MAP kinases and CDKs have diverse functions (Cook et al., Biochem. Soc. Trans. 2000, vol 28, pages 233-240). MAP kinase-induced pathways can inactivate CDKs (Fig. 1, p. 234); further, the role of MAP kinase itself depends on the duration and magnitude of activation (p. 236). Thus, the disclosed homology to these kinase families does not endow the polynucleotides with a well-established utility; such kinases have diverse functions.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25 and 27-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or

a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues, with respect to the enablement rejection of paper nos. 13, 18, and 22, that uses for the invention are described on pages 4, 5, and 31. Applicant argues that only one enabled use need be set forth.

Applicant's arguments have been fully considered but have not been found to be persuasive. What is set forth on pp. 4, 5, and 31 is that Mkinase is related to MAP kinases and to CDKs, and that it can be used to screen for modulators of the cell cycle. As stated above, however, the specification does not disclose the role of Mkinase in the cell cycle, nor does its identification as being related to MAP kinases and CDKs identify any particular use for it. Thus one of skill in the art would not know how to use the encoded protein to screen for cell cycle effectors; one of skill would not know what activity would be expected to be modulated, or how it would be modulated. Further, one of skill in the art would not, given the relationship with MAP kinases and CDKs, know how to use the protein or encoding polynucleotides, because, as set forth above, the functions of these kinases are diverse. Since neither the substrates nor the role of the protein in the cell cycle, nor the effects of its interaction with TRAF4 are known, there is no specific and substantial utility associated with the protein and the encoding polynucleotides and one of skill would not be able to use it.

NO CLAIM IS ALLOWED.

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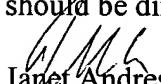
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Janet Andres, Ph.D.  
Patent Examiner

March 17, 2003